POC approved 3/24/08 mtheresee, HFS II

PRINTED: 03/20/2008
FORM APPROVED

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	NVN486ASC	A. BUILDING _____ B. WING _____	03/14/2008

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
SIERRA CENTER FOR FOOT SURGERY	1801 N CARSON CARSON CITY, NV 89701

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A 00	INITIAL COMMENTS This Statement of Deficiencies was generated as a result of a focus state licensure survey conducted at your agency on March 5, 2008 and March 14, 2008. The state licensure survey was conducted in accordance with Chapter 449, Surgery Centers for Ambulatory Patients. The findings and conclusions of any investigation by the Health Division shall not be construed as prohibiting any criminal or civil investigations, actions, or other claims for relief that may be available to any party under applicable federal, state, or local laws. The following deficiencies were identified.	A 00		
A 69	NAC 449.9812 Program for Quality Assurance 2. The program for quality assurance must include, without limitation: (g) Procedures for identifying and addressing any problems or concerns related to the care provided to patients using the medical records of the center and any other sources of data that may be useful to identify previously unrecognized concerns, and for assessing the frequency, severity and sources of suspected problems and concerns. The procedures must include, without limitation, procedures for assessing: (6) The procedures used to control infection. This Regulation is not met as evidenced by: Based on observations and interview it was determined that the facility failed to follow procedures to prevent the transmission of infections. Findings Include:	A 69		

If deficiencies are cited, an approved plan of correction must be returned within 10 days after receipt of this statement of deficiencies.

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE — TITLE: Medical Director, Owner — (X6) DATE: 3/23/08

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A 69	Continued From page 1 According to the Journal of Hepatology 48 (2008) 2-4 titled, Healthcare should not be a vehicle for transmission of hepatitis C virus, by Miriam J. Alter, "During the past 15 years, there have been more than 600 publications on the topic of nosocomial or iatrogenic hepatitis C virus (HCV) transmission not related to transfused blood, plasma-derived products, or transplantation (ISI Web of Science at http://portal.isiknowledge.com accessed October 19, 2007). Most of them were from developed countries, such as those in Western and Northern Europe, the United States, Australia, and Japan. The most compelling of these publications are those reporting the results of outbreaks involving patient-to-patient transmission, and virtually all of them had one common theme, unsafe therapeutic injections. Unsafe therapeutic injection practices resulted in common source exposures to contaminated multiple-dose medication vials and saline bags from re-insertion of used needles/syringes; use of a single needle/syringe to administer intravenous medication to multiple patients; and use of a single spring-loaded finger-stick device, without changing the platform, to monitor blood glucose in multiple patients." On 3/5/08 at approximately 11:10 AM, the director of nursing was interviewed. She stated that she began observing anesthesiologists for the reuse of syringes after her sister, who was in another state, informed her that an anesthesiologist had been fired for reusing syringes. She stated that some of the anesthesiologists that had been out of medical school for a long time would reuse syringes but the anesthesiologists that had been out of school for the past two to three years did not reuse syringes. She stated that an anesthesiologist was	A 69	A 69 The Director of Nursing (D.O.N.) and Medical Director (M.D.) took corrective action at the time of the incident 2 years ago. The anesthesiologist agreed to never again re-use any single-use item. He has been monitored and has not repeated the behavior. We now understand the incident should have been reported to officials at the time of occurrence.	

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A 69	Continued From page 2 observed reusing a syringe on different patients. She stated she confronted the anesthesiologist about his reuse of a syringe on different patients. She stated that he replied that he was going to continue the practice since he had been doing it for 20 years and no one was harmed. She revealed the name of the anesthesiologist that she had observed reusing syringes and stated the incident occurred approximately two years ago. She was asked if he had stopped reusing syringes since the confrontation. She stated that he had only come back to the facility about two times since the incident and she did not remember him reusing syringes. When she was asked if the practice of reusing syringes had stopped since the confrontation, she replied yes. On 3/5/08 at approximately 12:45 PM, the podiatrist asked what the findings had been so far. The podiatrist was informed that the director of nursing reported that an anesthesiologist had been observed reusing syringes between patients at the facility. He replied that some of the anesthesiologists did reuse the syringes at the facility. During a telephone interview on 3/12/08 at 2:45 PM, the podiatrist stated the anesthesiologist had started working at the facility in 1994. The podiatrist stated that he did not report the observation of the attempted reuse of the syringe by the anesthesiologist to the Board of Medical Examiners or to the Health Department. On 3/5/08 two reusable resuscitation bags were observed in the recovery area. During an interview on 3/5/08, the director of nursing stated the resuscitation bags were used about two times a year. She stated that after use the inside of the mask was wiped down with a disinfectant wipe.	A 69	A69 **On 3/5/08 the podiatrist told the surveyors he was aware that some anesthesiologists re-use single use items, and some believe it is safe to use them upstream on IV tubing. He apparently was not clear that he was speaking in general terms, and not referring to this facility. To clarify, he has never observed anyone re-use a single-use syringe or other single-use item, and is only aware of the single incident observed by the D.O.N.** **Policies and procedures have been clarified/ammended and include the following:** 1. **All anesthesiologists will read and sign an agreement to abide by specific safe anesthesia practices. (see exhibit #1) It will be signed in the presence of the D.O.N. or M.D. before any patient care is administered.** 2. **All medication delivery equipment is now stored in a separate basket for each patient. All opened or used equipment will be disposed of immediately after use. This will prevent re-use, and make any attempted re-use immediately identifiable.** 3. **All medications and delivery equipment is single use and will be disposed in appropriate hazardous materials container immediately after single use.** 4. **These policies/plans of correction are in effect from 3/6/08 forward. They were followed on 3/14/08, our next surgery day. The D.O.N (employee #1) is responsible for accomplishing and monitoring these policies/procedures. The Surgical Technician (S.T.) (employee #2) is responsible for ordering all single use medications and delivery equipment and maintaining adequate stock.**	

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A 69	Continued From page 3 She was not aware of the manufacturer's recommendation for disinfecting the bags after patient use. The bags were not being high-level disinfected after patient use and would be used again on another patient when needed. On 3/5/08, the director of nursing stated that the facility follows the Centers for Disease Control and Prevention Guidelines for infection control. The Centers for Disease Control and Prevention (CDC) Guidelines for Prevention of Nosocomial Pneumonia revealed, "Reusable resuscitation bags are particularly difficult to clean and dry between uses; microorganisms in secretions or fluid left in the bag may be aerosolized and/or sprayed into the lower respiratory tract of the patient on whom the bag is used; in addition, contaminating microorganisms might be transmitted from one patient to another via hands of HCWs." "These devices require either sterilization or high-level disinfection between uses on different patients." On 3/5/08 an observation was made of a tray of implantable screws. The surgical technician and director of nursing were interviewed regarding the use of implants at the facility. They stated that an anesthesiologist had informed them that screws and k-wires (Kirschner wires) were not considered implants. They stated that spore tests were not being run with each implant load and that the facility no longer maintained an implant log showing that implant loads had a spore test run with them in the autoclave. On 3/5/08, the manufacturers of both the k-wires and the screws confirmed that both items were considered implants via telephone interviews. The CDC's Disinfection and Sterilization of	A 69	A69 On 3/5/08 we were informed of recommended high-level disinfection of resuscitation bags and masks. On 3/7/08, we disposed of all of our re-usable resuscitation bags and masks. We ordered disposable resuscitation bags and masks, which arrived on 3/10/08, before our next surgery day. We now stock only disposable masks and bags, which will be disposed of immediately after single use. This policy is effective 3/10/08. The D.O.N. (#1) is responsible for accomplishing and monitoring this policy/procedure. The S.T. (#2) is responsible for ordering and maintaining adequate stock of disposable bags and masks. A69 On 3/6/08 we adopted the policy of running spore tests with every autoclave load that contains any implant. No implant will be used until it's spore test is negative for 48 hours. This was followed in preparation for our next surgery day (3/14/08). The S.T. (#2) is responsible for accomplishing this policy/procedure and now keeps record of each implant and its spore test results in a dedicated log book. The D.O.N. (#1) is responsible to monitor this by recording it in the implant log book and in the operating room record. Date of correction 3/10/08.	

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A 69	Continued From page 4 Patient-Care Equipment revealed, "Implantable items, such as orthopedic devices, require special handling before and during sterilization; thus, packs containing implantable objects need to be clearly labeled so they will be appropriately processed. To guarantee a wide margin of safety, it is recommended that each load of such items be tested with a spore test and that the sterilized item not be released for use until the spore test is negative at 48 hours." The Association of Operating Room Nurses (AORN), AORN 2006 Standards, Recommended Practices, and Guidelines regarding biological testing of implants revealed, "A biological indicator (preferably a process challenge device) should be included in all loads containing an implant(s), and the implant(s) should be quarantined until the results of the biological indicator are known." On 3/5/08, the autoclave's manufacturer's instructions were reviewed. The operator maintenance instructions revealed that, "The pressure relief valve must be checked each month by a qualified person to be sure that the relief valve is functioning properly." The surgical technician confirmed that this was not being done. On 3/14/08, observations were made in the pre-operative, nursing station/medication, and sterile processing areas, and the operating suite. General use, store brand (Costco Kirkland and Clorox, bleach free) disinfecting wipes were observed being used to wipe down surfaces in all these areas. On 3/14/08, Employee #4 was interviewed. She stated she used the Kirkland brand disinfecting	A 69	A69 On 3/5/08, the autoclaves' manufacturer's instructions were reviewed with our S.T. It was brought to our attention that the pressure relief valve was not being checked monthly. We have now adopted the policy of checking the function of the pressure relief valve as part of the monthly autoclave maintenance. The S.T. (#4) will be responsible for accomplishing this and will monitor it by recording it in the autoclave maintenance log book. Date of correction is 3/12/08.	

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A 69	Continued From page 5 wipes to wipe down all areas in the pre-operative area and the nursing station/medication areas. She stated she used the wipes after each patient in the pre-operative area, including the gurney and patient equipment. She also stated she used the same wipes to wipe down the nursing station at the end of the day. On 3/14/08, Employee #5 was interviewed. She stated that she used the Clorox disinfecting wipes to wipe down the counters of the clean sterilization area. On 3/14/08, Employee's #1 and #2 were interviewed at different times. Employee #1 stated that the Kirkland brand disinfecting wipes were used to wipe down the operating suite after each patient, and at the end of the day. This included the counters, lights, equipment, table surfaces, and buckets. Employee #2 confirmed that the Kirkland brand disinfecting wipes were used to wipe down the operating suite between patients. The Association of Operating Room Nurses (AORN), 2006 Edition, Standards, Recommended Practices and Guidelines revealed that horizontal surfaces in the operating room should be cleaned with an Environmental Protection Agency (EPA)-registered hospital disinfectant. It recommended that the cleaning be done before the first scheduled surgical procedure of the day and in between procedures. On 3/18/08, an epidemiologist from the CDC (Centers for Disease Control and Prevention) confirmed that an EPA-registered germicidal wipe was recommended for cleaning the areas between patients.	A 69	A69 We were following CDC guidelines for cleaning and disinfection of environmental surfaces (see Guideline for Prevention of Surgical Site Infections, CDC, April 1999). They recommend EPA-approved hospital disinfectant for disinfecting the floors and contaminated or visibly soiled surfaces. We use CaviCide, which is an EPA-approved hospital disinfectant. For all other surfaces, they do not recommend disinfection between procedures, just regular cleaning. We now know that these CDC guidelines conflict with The AORN recommended practices. We will now adopt the AORN recommendation of disinfection with EPA approved hospital disinfectant on all horizontal and other environmental surfaces before the first scheduled procedure of the day and between procedures. The Kirkland and Clorox disinfectant wipes were removed from the operating room and will be replaced with CaviCide or equivalent EPA-approved hospital disinfectant. We appreciate this being brought to our attention. Policy effective 3/17/08 and will be corrected by 3/27/08, the day before our next scheduled surgery day. The S.T. (#2) is responsible for accomplishing this, and monitoring will be done by the D.O.N. (#1). We have also found a certified sterile processing and infection control consultant who will conduct a training course with our surgery center staff and review our policies and procedures for infection control and sterile processing. We are also looking for a formal certification course for our staff.	

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A 69	Continued From page 6 A general use, household disinfectant wipe (such as the Kirkland and Clorox disinfecting wipes used by the facility) does not meet this recommendation. Severity: 3 Scope: 3	A 69		
A112	NAC 449.9855 PERSONNEL 2. Each employee of the center must: (a) Have a skin test for tuberculosis in accordance with NAC 441A.375. A record of each test must be maintained at the center. This Regulation is not met as evidenced by: Based on record review and interview, it was determined that the facility failed to provide documentation of two- step tuberculin skin test on 4 of 5 employees, and failed to provide evidence of an annual one-step tuberculin skin test on 5 of 5 employees. Findings include: A review of the personnel files of Employee's #1, 2, 3, and 4 revealed there was no evidence of a two-step tuberculin skin test. All of the employees had been hired in excess of one year. A review of the personnel files of Employee's #1, 2, 3, 4, and 5 revealed that the last annual one-step tuberculin skin test was done on January 12, 2007. An interview with the director of nursing revealed the tests were not available. Severity: 1 Scope: 2	A112	A 112 Tuberculin skin tests were administered to all surgery center employees on 3/19/08, and read on 3/21/08. All were negative. The second step of the two-step test will be administered next week. Employee #4 had her two-step test done at her other workplace, but was not in her file. It has been added to her file. Employee #3 is not able to have tuberculin skin tests because of a medical problem and has a current chest X-ray instead. Our policy was re-emphasized to keep tuberculin testing up to date for all surgery center employees, and be sure they are in their personnel files. The D.O.N. is responsible for accomplishing this and monitoring it. Date of correction began 3/19/08 and will be complete on 3/29/08 and thereafter.	

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A118	Continued From page 7	A118		
A118	NAC 449.9855 Personnel 3. A current and accurate personnel record for each employee of the center must be maintained at the center. The record must include, without limitation: (d) Such health records as are required by chapter 441A of NAC. This Regulation is not met as evidenced by: Based on record review, it was determined that the facility failed to provide evidence of a preemployment physical examination on 1 of 5 employees. Findings include: A review of the personnel file of Employee #3 revealed there was no evidence of a preemployment physical examination in the record. Severity: 1 Scope: 1	A118	A 118 All required health records are in the personnel files and were at the time of our inspections (3/5/08 and 3/14/08). Employee #3 has a pre-employment history and physical exam, signed by Dr Easley, dated 7/10/02 in her file. Her file also contains chest X-ray report and current X-ray bone survey. See exhibit #2 (please black out name of employee for privacy purposes.) Policy re-emphasized and re-implemented 3/17/08. We welcome City, State, and Medicare surveyors and thank them for their recommendations. We regret all misunderstandings that occurred during the process. We are dedicated to doing our utmost to be in full compliance with all guidelines, standards, and recommendations. We thank the community for their continued trust. We want to express that our sincere desire is to relieve people's pain and suffering, and to do it in the safest manner possible.	

Exhibit #1, ID Prefix Tag A69

Anesthesia Policy and Procedure Statement

As an anesthesia provider at Sierra Center for Foot Surgery, I agree to follow all basic standards of care as set forth by the American Society of Anesthesiologists (ASA). These standards will include, but are not limited to the following:

1) Pre–operative evaluation: all patients to receive any type of anesthetic will be interviewed by the anesthesia provider prior to induction. At a minimum this includes: basic H&P, NPO status, drug allergies, review of baseline vital signs. Provider is to ensure patient is safe to proceed with anesthetic.
2) Ensure that Anesthesia informed consent has been signed (can be included in surgical consent).
3) Patient monitoring: all patients will have continuous monitoring of respirations, 02 saturation, BP and EKG throughout entire administration of propofol. At no time may the anesthesia provider leave the patient unattended during anesthesia delivery.
4) BP and HR must be taken and recorded at a minimum of every 5 minutes.
5) Anesthesia provider will adhere to strict standards regarding infection control. This will include all ASA guidelines, universal precautions, etc. and will include specifically:
    - All syringes, needles, IV tubing, anesthesia tubing and propofol and other medication vials are to be used on one patient only. There will be no transfer of any of these items for use on another patient. I understand that my failure to adhere to this guideline may lead to the spread of infectious disease from one patient to another and is in strict violation of ASA practice guidelines and the guidelines of this surgery center.
    - Provider will ensure that anesthesia work area is clean between cases.
    - Oxygen delivery devices such as masks and nasal cannulas are one time use items.
6) Anesthesia provider agrees to remain at the facility until all patients having received an anesthetic have met discharge criteria and patient care can safely be transferred to a physician or registered nurse.
7) Anesthesia provider to have current licensure to practice anesthesia.

I understand that I have been consulted to provide anesthesia services for Sierra Center for Foot Surgery and in so doing agree to follow basic standards of care as set out by the ASA. I have current knowledge and understanding of these guidelines and understand that any failure on my part to follow these guidelines may result in harm to the patient. I will not hold Sierra Podiatry Center or its employees responsible for any negligence on my part in providing anesthesia.

Signed:_____ Date:_____